



Briefing Paper

SECTION 75 REGULATIONS MOTION - HOUSE OF LORDS 24th APRIL 2013

SI 2013/500 NHS (Procurement, Patient Choice & Competition) (No 2)

Royal College of General Practitioners

Overview

The RCGP urges Peers to support the motion calling for the annulment of the National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations (S1 2013/500).

We believe the Regulations should be annulled because:

- The current wording of the regulations risks creating unnecessary legal uncertainty about the circumstances in which CCGs will be able to choose not to put services out to tender.
- The regulations retain Clause 5, which appear to imply that, if commissioners decide not to put a service out to tender, they must be satisfied that there is only one provider capable of delivering that service. This is a very narrow test which, if applied, will severely restrict the freedom of Clinical Commissioning Groups (CCGs) to make decisions that they feel are in the best interests of patient care.
- We welcome the inclusion within the regulations of new provisions to ensure services are provided in an integrated way (Clause 2), and permitting commissioners to engage in anti-competitive behaviour if it is in the interests of patients (Clause 10). However, it remains unclear whether these will have the effect in law of allowing commissioners more freedom than they appear to be being given in Clause 5.
- The wording of the regulations themselves is of critical importance. Whilst forthcoming guidance from the regulator, Monitor, will help clarify the practical implications of the regulations to some extent, the contents of this guidance will not be able to prevent CCG decisions from being subject to legal challenge in the courts.
- Even if the Government's interpretation of the regulations is correct, the potential threat of legal challenge may mean that CCGs decide to take a cautious approach to implementing the regulations, creating a presumption in favour of putting services out to competitive tender.
- The current version should be annulled and a new, clearer wording established to ensure patients and commissioners have confidence in the new system.

Background to the Regulations

These regulations will be pivotal to shaping how the Health and Social Care Act 2012 is implemented in practice, and will have a direct impact on patient care. It is therefore essential that the regulations are clear and robust to ensure that commissioners can have confidence that their decisions will not be subject to legal challenge.

A summary of the life of the regulations so far:

- **13th Feb** – Government table first version of the regulations.
- **28th Feb** – RCGP Chair Dr Clare Gerada writes to Earl Howe expressing concerns about the potential impact of the regulations on commissioners' freedom to choose not to put services out to competitive tender. View letter [here](#).
- **7th March** – A House of Lords Secondary Legislation Scrutiny Committee [report](#) concludes that *"It is clear that from the degree of concern in the health sector and beyond that the Department will have a major task in explaining these provisions to health staff and persuading them to accept their interpretation of them"*.
- **11th March** – The Government withdraws the first version of the regulations in light of the concerns raised and publishes a second version with some changes.
- **14th March** – RCGP Chair Dr Clare Gerada writes to the House of Lords Secondary Legislation Committee expressing our view that the Government's changes to the regulations do not fully address the concerns we originally set out (especially the retention of Clause 5). View letter [here](#).
- **21st March** – A House of Lords Secondary Legislation Committee [report](#) on the second version of the regulations concludes that: *"The wide range of interpretations of the substitute Regulations is, we believe, likely to translate into uncertainty about how they will operate and will, in turn, result in commissioners conducting unnecessary tendering processes simply to ensure that their decision will be "safe" under the law."*
- **24th April** – With the Government having made clear that it does not intend to review the regulations in light of the ongoing concerns raised by RCGP and others, the House of Lords will vote on a motion to annul the regulations.

There have been a variety of legal opinions and counter-opinions produced concerning the effect of the revised regulations. Legal advice commissioned from David Lock QC and Ligia Osepciu (available online [here](#)). This has received a [response from the Department of Health](#), to which David Lock has in turn published a [rebuttal](#).

Why the regulations will restrict the freedom of CCGs

Having looked closely at these regulations, the RCGP believes that they do not go far enough in ensuring that commissioners are genuinely free to decide whether or not to expose services to competition.

Retention of Clause 5

Whilst the current (second) version of the regulations is in some ways a step in the right direction (e.g. the inclusion of an explicit mention of integration in Clause 2), the retention of Clause 5 of the original regulations withdrawn by Government means that the regulations continue to imply that commissioners must be *"satisfied that the services to which the contract relates are capable of being provided only by that provider"* when choosing not to put a service out to competitive tender.

We remain concerned that this will give rise to circumstances in which CCGs feel they must put a service out to competitive tender because technically more than one provider is capable of delivering it, even if they feel it is not in the interests of patients to do so. Without clear evidence that there is genuinely only one provider that can deliver a service, it is likely that CCGs will err on the side of caution, effectively creating a presumption in favour of competition.

According to recent research by NHS England and Monitor on choice and competition in the NHS, less than 3% of the £46 billion budget that local commissioners spent on commissioning clinical services in 2010/11 involved the use of a competitive tender or local Any Qualified Provider (AQP) to secure services. If commissioners are required to routinely put services out to tender, this would represent a radical and far-reaching change in the way NHS services are commissioned.

In practice, the circumstances in which services are capable of being provided by a single provider are likely to be limited. Whilst this may be true in some rural locations, for most services it is hard to see how it could be the case in urban areas with multiple potential providers. The RCGP has put together a number of case studies of the kind of situation in which we believe the regulations, by constraining the freedom to decide not to put services out to tender, could prevent commissioners from acting in the best interests of patients. These are included as an annex below.

There may be very good reasons why commissioners do not want to put new contracts out to tender. Commissioners may feel that the incumbent provider is offering an excellent service and that the costs of a competitive tendering exercise would outweigh any potential benefits to patients. Alternatively, commissioners may decide that it is in the interests of the populations they serve to protect the continued viability of services at their local hospital. It remains unclear, however, whether commissioners will be able to exclude services from competitive tender on such grounds. **We urge the Government to remove Clause 5 from the regulations.**

Tension between Clause 5 and other parts of the regulations

We have welcomed changes to the regulations stipulating that commissioners must ensure services are provided in an integrated way (Clause 2), and that they may engage in anti-competitive behaviour if it is in the interests of patients (Clause 10). The Government has argued that these changes mean that the narrow definition set out in Clause 5 will not, in practice, always apply. However, there is (as the Lords Secondary Legislation Scrutiny Committee has noted) a divergence of views on the legal implications for CCGs, suggesting that there is a risk that the Government's interpretation of the regulations could be overturned in the courts. Removing Clause 5 would avoid this unnecessary risk.

The relationship between the regulations and existing procurement requirements

The Government has stated that the regulations simply reflect the requirements of existing EU and UK procurement law (in particular the provisions of the public contract regulations 2006) and that in the absence of the regulations these would continue to apply to the NHS.

Whilst pre-existing procurement guidance does state that where commissioners decide to procure through a single tender they must be able to demonstrate that there is only one capable provider, this was not binding in the same way as the proposed new regulations will be. Commissioners could choose to depart from the previous procurement guidance if they had good reason to do so. Indeed, according to the guidance itself: *"It remains a matter for PCTs to*

determine when and how to use procurement as a tool for securing commissioning requirements and the onus is therefore on PCT Boards to demonstrate a rationale for their actions and decisions (e.g. Tender/No Tender decisions.)”

The impact of Monitor’s approach to enforcement of the rules

The Government has stated that the regulations should be viewed in the light of the existence of a sector specific regulator with expertise in healthcare in the shape of Monitor. Monitor will be required to publish guidance explaining how it will use its investigative and enforcement powers under the regulations, designed to reduce uncertainty for commissioners and give them greater confidence that decisions in patients’ best interests should not lead to regulatory intervention.

However, this guidance will, by definition, be inferior in law to the regulations – a court will only attach weight to guidance if the wording of the governing regulation is unclear. Even if Monitor were to adopt an enforcement regime that allowed commissioners a greater degree latitude than the text of regulations in deciding whether to tender, if challenged such a “light” enforcement approach would be highly likely to be overturned by the courts on the grounds of unlawfulness. The contents of any Monitor guidance would be unable to prevent this.

Monitor guidance

RCGP will input our views into Monitor’s forthcoming consultation around these proposed guidelines. Whilst we would strongly prefer to see changes made to the procurement regulations themselves, if this does not take place we urge Peers to seek assurances from Ministers that Monitor’s guidance will:

- Make it clear that commissioners can choose not to put a service out to competitive tender if they feel patient care is best served by not doing so, even if this contravenes Clause 5.
- Make it clear that where CCGs are satisfied that an existing service provider whose contract is coming to an end is performing well and that to retain this provider without a competitive tender would be in the best interests of patient care, they can do so within the framework of the regulations.

Contact RCGP

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Annex: Case Studies – How will the proposed Health and Social Care Act regulations affect CCG autonomy?

Below are six hypothetical scenarios in which Clinical Commissioning Groups (CCGs) may find themselves in future. RCGP is concerned that under the *National Health Service (Procurement, Patient Choice and Competition) Regulations 2013* currently laid in Parliament, the commissioners in these scenarios may find their freedom to decide not to expose services to competition is restricted. All these examples are based on the premise that the CCG has a well worked out market strategy and intervention time line agreed in open session by the CCG Governing Body and the local Health and Wellbeing Board aligned to the Joint Strategic Needs Assessment (JSNA). Within the market strategy and five year financial model a CCG has set aside a budget to support procurement but this has to come out of the CCG's £25/head management costs.

These hypothetical scenarios are designed to test how much control the local CCG with support from the Health and Wellbeing Board actually has to develop a locally integrated system or whether the regulations inadvertently mean they find themselves forced to go to the market.

Case 1: The responsibility for commissioning community sexual health services moves to a Local Authority who decide to enter into a joint commissioning arrangement with the CCG. The five year contract has come to an end but the CCG and Local Authority feel happy with the current service with high patient satisfaction, good integration with other services, outcome targets for reducing sexual transmitted infections met, improving reductions in teenage pregnancy and improved Chlamydia screening within a reduced budget. Both the CCG and Local Authority feel that AQP is not appropriate and the risk of fragmentation and expense of a full retender is greater than continuation with the existing provider. They decide to extend the contract. This view is supported by the local Health Watch. Would they, despite the circumstances, be forced by the regulations to go to market or could they proceed as planned?

Case 2: The CCG agrees a very new specification with improved access times and educational feedback for diagnostic (radiology) services within their acute trust. This is within the Payment by Results tariff with agreement to unbundle tariffs and will be managed as a separate sub contract with the provider trust but still within the main "shell" contract for governance purposes. Diagnostics is not on the time line for an intervention decision for another five years. The CCG has analysed the wider diagnostic market but feels the local agreement already give significant added value. Would the CCG be forced by the regulations to go to AQP or tender in the open market?

Case 3: The CCG is commissioning community nursing within a block contract. This service has changed out of all recognition with the development of risk stratification and personalisation. Community nursing is well integrated with the practices, social services and other specialist community services. The CCG and Local Authority, practices and local acute providers feel the system risk of a new provider is too great and decide to continue with the current contract without going to market at this stage. Would this be challenged within the regulations?

Case 4: A CCG is commissioning an INR (anti-coagulation) locally enhanced service from its local practices. The CCG's view is the lower cost and direct link to dosage and clinical responsibility means the GP practices continue to be the provider of choice by virtue of the registered list. This view has been tested independently to avoid Conflict of Interest and subsequently agreed by the Health and Wellbeing Board. The CCG plans therefore not to put this out to market but continue with current arrangement of contracting with the local practices.

Would this be challenged under the regulations?

Case 5: A PCT went out to market three years ago for a community dermatology service. The procurement costs were high but in the end a new provider was chosen and is now well integrated with local practices leading to lower costs, educational sessions with primary care and good effective links with third sector organisations. The contract is due to come to an end but the CCG feels that as the service is working well, the cost of completely new tender would be high and have decided after analysing the market, they would prefer to stay with the current provider. This view is supported by the Health and Wellbeing board. Would the regulations force the CCG to go out to market?

Case 6: A large practice working on the boundary of a CCG decides to move from one CCG to another by mutual agreement when it is found that the majority of its patients have shifted over time. This means activity numbers and revenue in the schedules need to change by virtue of a change in CCG population size by 5%. Would this have any impact on the need to go to market?